K100470

510(k) Summary

APR 21 2010

Submitter:	Medtronic Vascular 35-37A Cherry Hill Drive Danvers, MA 01923
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Date Prepared:	April 19th, 2010
Trade Name:	Medtronic GTX Guidewires
Common Name:	PTCA Guidewire
Classification Name:	Wire, Guide, Cardiovascular 21 CFR 1330, Product Code DQX
Predicate Devices:	Medtronic GTX Guidewire (K091582)
Device Description:	The Medtronic GTX 12 guidewires are available in nominal 180cm length and 300cm exchange length. They are available with PTFE, silicone or hydrophilic coatings. A portion of the distal length is opaque to allow for visualization under fluoroscopy and markers are etched on the proximal segment of the guide wire to aid in gauging guide wire position relative to the guiding catheter tip.
Statement of Intended Use:	Medtronic GTX Guidewires are steerable guide wires that are used for the introduction and placement of diagnostic or interventional devices in the coronary and peripheral vasculature and may be used to reach and cross a target lesion. Medtronic guide wires are not intended for use in the cerebral vasculature. Medtronic steerable exchange wires are used to facilitate the substitution of one diagnostic or interventional device for another.

Summary of Technological Characteristics:

The Medtronic Vascular GTX 12 Guidewire consists of a corewire covered with spring coils and terminated in a hemispherical tip, which impart various characteristics to the distal tip of the wire, such as tip stiffness. Wire coatings provide sufficient lubricity to reach and cross target lesions. Markers on the proximal portion of the corewire aid in gauging guide wire position relative to the guiding catheter tip. The technological characteristics of the Medtronic GTX-12 guidewire are identical to that of the Medtronic GTX guidewires (K091523).

Summary of Non-clinical Data:

In-vitro bench testing was conducted according to the recommendations from relevant FDA guidance to demonstrate that the GTX 12 guidewire met the acceptance criteria and performed similarly to the predicate devices. As noted below, in some cases a bracketing sample strategy was chosen to support the test requirements. The *in-vitro* tests that were conducted to evaluate the performance of the GX 12 guidewire include:

***In-vitro* Bench Testing Performed**	**Product Tested**
Dimensional—Diameter	Medtronic GTX 1 (K091582) and GTX 15
Dimensional—Diameter (GTX guidewires with a 0.009" tip joint only)	Medtronic GTX 15
Dimensional—Overall Length	Medtronic GTX 1 (K091582) and GTX 15
Dimensional—Radiopaque Length	Medtronic GTX 1 (K091582) and Medtronic GTX 15
Tip Column Stiffness	Medtronic GTX 12
Tortuous Torque Energy Transfer	Medtronic GTX 12
Tip Integrity-Torsional	Medtronic GTX 1 (K091582) and GTX 15
Tip Integrity-Strength	Medtronic GTX 1 (K091582) and GTX 15
Radiopacity-Distal & Proximal	Medtronic GTX 1 (K091582) and GTX 15
PTFE Coating Adhesion	Medtronic Cougar XT (K032899)
Lubricity/ Durability	Medtronic Cougar XT (K032899)
DOC Insertion and Extraction Force (180 cm only)	Medtronic GT1 (K983927)
DOC Crimp Wire Stiffness (180cm only)	Medtronic GT1 (K983927)

Due to shared materials of construction, biocompatibility testing was performed on the predicate Medtronic GTX guidewires (K091582) to satisfy the requirements of *ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing*. The following biocompatibility tests were performed:

- IS0 Cytotoxicity Study
- IS0 Maximization Sensitization Study
- IS0 Intracutaneous Study Extract (SC & SO)
- ISO/USP Systemic Toxicity Study (SC & SO)
- USP Material Mediated Pyrogen Study
- ASTM Hemolysis Study
- Compliment Activation (C3a & SC5b-9)
- *In-vivo* Thromboresistance Study
- Plasma Recalcification

Simulated Use Testing (Animal Study) was also performed using the GTX 12 guidewire.

No new safety or effectiveness issues were raised during the testing.

Summary of Clinical Data:

No clinical investigation has been performed for this device.

Conclusion from Data:

Medtronic has demonstrated that the GTX 12 Guidewire is substantially equivalent to the predicate devices based on its indications for use and fundamental scientific technology. Testing demonstrates that the GTX 12 Guidewire device is safe, effective and performs as well or better then the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR 21 2010

Medtronic Inc.
c/o Ms. Colleen Mullins
Senior Regulatory Affairs Specialist
37A Cherry Hill Drive
Danvers, MA 01923

Re: K100470
Trade/Device Name: Medtronic Vascular GTX 12 Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: March 23, 2010
Received: March 25, 2010

Dear Ms. Mullins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number K100470 :

Device Name: Medtronic GTX 12 Guidewires

Indications for Use:

Medtronic GTX guide wires are steerable guide wires that are used for the introduction and placement of diagnostic or interventional devices in the coronary and peripheral vasculature and may be used to reach and cross a target lesion. Medtronic guide wires are not intended for use in the cerebral vasculature. Medtronic steerable exchange wires are used to facilitate the substitution of one diagnostic or interventional device for another.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices

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